



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/609,194

06/26/2003

Daniel J. Potter

11533US.00

7602

36802 7590 10/01/2008

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

BHATIA, AARTI

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

This Office Action is based on the 10/609,194 application filed on 06/26/2003.

Claims 1-12, as amended on 9/04/2008, are currently pending and have been considered below.

Response to Amendment

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,312,355 to Lee in view of U.S. Patent No. 6,083,207 to Heck.

Lee discloses a tearable hemostasis valve (14) comprising: a valve body (16); a first and second grip tab (38, 40) attached to said valve body at a first and second point (it is the Examiner's position that the interior of the grip tabs contact the valve body in the general center area of the valve assembly, the center axis being substantially a

Art Unit: 3763

common point for the grip tabs to meet); a score line (42) disposed on said valve body between said first and second points; a first self-sealing membrane (22) disposed within said valve body; and a snap-fit arrangement coupled to a distal end of said valve body (see 16b in figure 2), wherein said snap-fit arrangement comprises a cavity disposed in said valve body; and an annular sidewall (see base of 16b) defining an opening in communication with said cavity, further comprising a score in said first membrane (column 8, lines 1-2).

Lee teaches wherein the snap and fit arrangement is adapted to couple into an **inner** surface of an annular hub of a proximal end of a tubular medical device rather than onto an **outer** surface of the hub.

Heck teaches a hemostasis valve wherein the diameter of said opening formed by said annular sidewall is less than a diameter of said cavity (see figure 3) so that the valve assembly is adapted to snap fit onto an **outer** surface of a hub (see figure 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tearable valve of Lee with the snap fit arrangement of Heck to be able to use the valve in conjunction with a splittable sheath having a hub with tabs (see figure 2).

Lee and Heck teach the hemostasis valve as generally claimed, but fail to teach a second membrane in the valve assembly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a second membrane in the valve assembly, since it has

been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

4. Applicant's arguments filed 7/11/08 and 9/04/08 with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763